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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,786	06/05/2006	Gerard Cousin	065691-0432	3644

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EXAMINER	
BAEK, BONG-SOOK	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
10/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,786	COUSIN ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-19* is/are pending in the application.

4a) Of the above claim(s) *10-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-9, and 18-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment filed on July 2, 2009 is acknowledged. Claim 2 has been cancelled and claims 10-17 have been withdrawn. Claims 18-19 and claims 1, 3-9 and 18-19 are under examination in the instant office action.

Applicants' arguments, filed on July 2, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. A new ground of rejection is necessitated by new claim 18. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "derivatives" is not clearly defined in the specification, and therefore does not set forth the metes and bounds of the term "derivative". The 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield,

Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "sugar derivatives". Thus, it is unclear and indefinite as to how the "derivative" herein is encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-9 and 18-19 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,027,747 (Issue date: 2/22/2000) in view of Us patent 4,016,254 (Issue Date: 4/5/1977).

US 6,027,747 teaches a solid dispersion of at least one therapeutic agent preferably hardly water-soluble active ingredients in a hydrophilic carrier, made by the process comprising

dissolving at least one therapeutic agent in a volatile organic solvent with a hydrophilic polymer such as polyvinylpyrrolidone, and evaporating the solvent to dryness to form a co-precipitate of therapeutic agent and hydrophilic polymer (abstract, column 3, line 49-column 4, line 8, and column 7, lines 50-column 8, line 8) and this process provide a novel process for dry pharmaceutical products and the co-precipitate formed thereby which has faster and greater resorption when administered orally (column 2, lines 17-20). It further teaches that a surface-active agent such as non-ionic surface agent is further added (column 3, lines 33-38) and the organic solvent is selected from ethanol, isopropanol, tetrahydrofuran, isopropyl ether, acetone, methy ethyl ketone, tetrahydropyran, or chlorinated solvents such as methylene chloride or even mixtures in various proportions of these same solvents (column 3, lines 21-31). In addition, US 6,027,747 discloses that the coprecipitates comprising fenofibrate (active substance), poyvinylpyrrolidone (hydrophilic polymer), and Tween 80 (surface-active agent) dissolved in absolute ethanol are sprayed on neutral pellets of carbohydrates (neutral hydrophilic carrier) such as levulose, lactose, arabinose, mannose, sorbose, cellulose and its derivatives, starch, dextrins and the like, which are sugar derivatives, and the sprayed granules are dried on a fluidized bed dryer (column 19, line 20-column 20, line 6 and claim 2). It further teaches that the poyvinylpyrrolidone has a molecular weight ranging from 10,000 to 50,000 (claims 1 and 8). These teachings read on the limitation of claims 18-19.

The reference differs from the instant invention insofar as it does not state milling step and the repetition of spraying and milling.

US patent 4,016,254 teaches that the processing of medicaments from the initial production of the compound to the formulated product ready for use normally involves a milling

stage, and further teaches that milling is included to reduce the particle size of the medicament, to improve the drying rate of the material, to aid in blending operations, to increase the bioavailability of the medicament from the formulation or for various other reasons (column 1, lines 56-63).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the invention was made to repeat spraying and milling steps for the process of making a particle as taught by US 6,027,747 since the person skilled in the art would have expected that the repetition of spraying and milling steps ensures the particles to possess adequate amount of active substance as well as even distribution and to have an optimum particle size for bioavailability and absorption in view of teachings of Us patent 4,016,254 and US 6,027,747.

In the alternative, when the prior art already teaches an almost identical process of making particles using the same ingredients, adding spraying and milling steps one or more times, which are well-known process in the pharmaceutical art, would be obvious and not considered to be inventive, unless the applicants present data showing that the process having the claimed feature (repetition of spraying and milling) provides unexpected properties or effect on the resulting product compared to the process of US 6,027,747.

Response to Applicants' argument:

Applicants argued that Seager discloses that milling presents drawbacks in yielding "disadvantageous dust", thus a person of ordinary skill in the art would not be led to carry out multiple milling steps yielding the drawback of dust formation with no expectation of any benefit. Although Seager discloses a disadvantage of dust formation, it teaches more advantages

of reducing the particle size of the medicament, improving the drying rate of the material, aiding in blending operations, and increasing the bioavailability of the medicament and it also states that processing of medicaments from the initial production of the compound to the formulated product ready for use normally involves a milling stage as stated in the previous office action mailed on 1/16/2009. Thus, the skilled artisan who is interested in making better particles for a pharmaceutical formulation would still have been motivated to carry out milling steps on the expectation that it would be beneficial for reducing particle size, improving the drying rate of the material, aiding in blending operations, and increasing the bioavailability.

Applicants also argued that the claimed invention yields less agglomerization and improved dissolution profile referring to page 1, paragraph [0018], page 5, [0125] and Figure 2. However, a mere statement without factual evidence is not persuasive. In addition, the dissolution profile shown in Figure 2 does not provide any clear evidence that the process having the claimed feature (repetition of milling) provides unexpected properties or effect on the resulting product compared to the process of US 6,027,747 since there is no significant difference in dissolution rate between "before final milling and "after final milling". Furthermore, improved dissolution rate after milling would have been expected by reducing particle size in view of US patent 4,016,254

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-9 and 18-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 10/564845. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application 10/564845 anticipate the instant claims. The claims of copending Application No. 10/564845 are drawn a

process of making a particle composition comprising a specific active substance such as antiviral pyrimidine or triazine while the instant claims are drawn to the same process of making a particle composition containing any active substance. "A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slater*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); *In re Gustily*,
872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (Gustily claimed a genus of 21 specific chemical species of bicyclical thia-aza compounds in Markush claims. The prior art reference applied against the claims disclosed two of the chemical species. The parties agreed that the prior art species would anticipate the claims unless applicant was entitled to his foreign priority date.).

This is a provisional obviousness-type double patenting rejection.

Response to Applicants' argument:

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but the rejection will be maintained in this Office Action and future Office Actions until withdrawn since Applicants have not presented a terminal disclaimer, the claims of the above co-pending rejection remain pending, and this is not the only or sole rejection remaining.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-071818. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
/Bbs/

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